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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/085,738	02/28/2002	Kevin S. Weadock	15314 (ETH-1636)	8872
<div>7590 Scully, Scott, Murphy & Presser 400 Garden City Plaza Garden City, NY 11530</div>			<div>EXAMINER EREZO, DARWIN P</div>	
			<div>ART UNIT 3773</div>	<div>PAPER NUMBER</div>
			<div>MAIL DATE 11/14/2007</div>	<div>DELIVERY MODE PAPER</div>

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/085,738

Applicant(s)

WEADOCK ET AL.

Examiner

Darwin P. Erez

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3773

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 14 September 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-11 and 14-43 is/are pending in the application.
- 4a) Of the above claim(s) 3, 10, 11, 16-28 and 34-37 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1, 2, 4-9, 14, 15, 29-33 and 38-43 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 9/14/07 has been entered.

Claim Rejections - 35 USC § 102

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

3. Claims 1, 2, 4, 5, 7-9, 14, 15, 29-33, 38, 39 and 41-43 are rejected under 35 U.S.C. 102(e) as being anticipated by US 6,726,923 to Iyer et al.

(claim 1) Iyer discloses a device for creating an end to side anastomosis between a first **30** and second **28** vessels (Fig. 7 and 8), the device comprising an extravascular body **26** with at least a portion formed from a resorbable sponge (collagen; col. 11, line 3). Iyer discloses a multilayer body comprising collagen, which is a sponge, and a PTFE. This multilayer body is then rolled to form a tubular body having an end or outer

surface that forms the outer profile of the body, and an opening or inner surface. The device is then attached to an anastomosis site so that the first vessel **30** is located within the opening and that the device also attaches to the second vessel **28**. The device is secured via adhesives along its free edges, which would include surfaces for both the first and second vessel. This is viewed as the first and second securing means. See col. 10, line 65 to col. 11, line 20.

(claim 2) Iyer discloses that the body could have a tubular structure or variations thereof (col. 11, line 10). Thus, it is inherent that a disk-shape is a variation of a tubular structure because it is merely a section of a tubular structure.

(claims 4 and 5) The outer surface of the first vessel is adhered to the inner surface of the opening, as cited in the rejection to claim 1. Furthermore, the device also comprises fibrin for increase adhesion to the vascular wall (col. 11, line 64-66). This adhesive seals the outer surface of the first vessel to the opening.

(claim 7) The outer edges of the body is adhered via adhesive to the outer surface of the second vessel, as cited in the rejection to claim 1.

(claim 8) The inner surface of the opening includes adhesive.

(claim 9) The inner surface is made of collagen, which is porous, and would also include the adhesive as cited in claim 1.

(claims 14 and 15) The collagen includes a medicament, such as an anastomosis modulating agent (see abstract).

(claims 29, 30, 38, 39 and 41) Iyer further discloses a method comprising adhesively attaching the device of claim 1 to both the first vessel **30** and the second

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vessel **28** to create an anastomosis site between the two vessels; wherein the device has an opening for receiving the outer surface of the first vessel (see Fig. 7 or 8); wherein the device seals the outer surface of the first and second body since the entire free edge of the device is adhered to both vessels; wherein the hole of the first vessel would be aligned with the opening of the device.

(claims 31-33) It is inherent for the second vessel to include a hole prior to anastomosis since an end-to-side anastomosis device attaches the free end of the first vessel to the hole in the second vessel.

(claims 42 and 43) See Fig. 7 and 8. Blood flow **34**.

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. Claims 6 and 40 are rejected under 35 U.S.C. 103(a) as being unpatentable over Iyer et al. in view of US 2002/0065545 A1 to Leonhardt et al.

Iyer discloses all of the claimed features of the invention (as detailed above), including adhering the device to both the first and second vessels. However, Iyer invention fails to disclose using a balloon catheter to urge the outer surface of graft vessel against body, compressing the adhesive between them. However, Leonhardt discloses a graft vessel **24** and a body (**10**, aorta) and discloses inserting and expanding a balloon inside of graft vessel in order to urge the outer surface of the graft vessel

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against body 10 to sandwich the adhesion (glue, 56) therebetween (paragraphs [0027, 0028, 0030, 0060, 0083]; Figs. 1, 9d, 10a). Leonhardt teaches that one should use a balloon catheter in order to secure the outside surface of graft vessel ("spring means" 26 specifically and member 24 generally) to the interior surface of body (10) (paragraph [0030], last sentence). Therefore, it would have been obvious to one having ordinary skill in the art at the time of the invention to employ a balloon catheter to better secure vessel (10) to body (18), sandwiching adhesive therebetween, as taught by Leonhardt, because a balloon catheter expands the inner member towards the outer member and will cause them to touch and be secured to each other by glue.

Response to Arguments

6. Applicant's arguments filed 09/14/07 have been fully considered but they are not persuasive.

The applicant amended the claims to recite the limitation "the outer surface forms the outer profile of the body". It was then argued that Lyer fails to disclose a second securing means which secures a portion of the second vessel to a corresponding portion of the outer surface forming the outer profile of the body" (page 12 of remarks). However, this is not persuasive because the invention of Lyer still anticipates the amended limitation.

As stated in the rejections above and shown in the figure below, Lyer discloses the device having the following:

-an outer surface (any external surface) having a portion that defines the outer profile of the device,

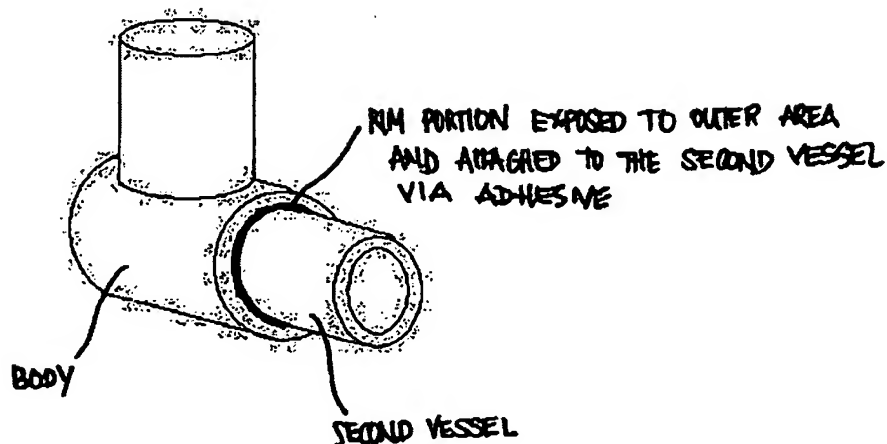
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-another "portion" of the outer surface (external surface) being attached to the second vessel.

As stated in the claims, only a "portion" of the outer surface is secured to the second vessel. It does not specify which portion of the outer surface is secured to the second vessel. Therefore, it is the examiner's position that the device of Lyer has an outer surface having a portion that defines the outer profile of the device and another portion being secured to the second vessel.

It should also be noted that the limitation of the outer surface defining an outer profile of the body does not impose any specific structural limitations to the device. That is, any portion of the outer surface can impose an outer profile of the device, even the edge shown in the illustrated figure below.

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Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Darwin P. Erez who's telephone number is (571) 272-4695. The examiner can normally be reached on M-F (8:00-4:30).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jackie Ho can be reached on (571) 272-4696. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Darwin P. Erezol/
Examiner
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